IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OKLAHOMA

In re: Genentech, Inc., Herceptin (Trastuzumab) Marketing and Sales Practices Litigation	)	MDL Docket No. 16-MD-2700
	)	Document Relates to: **All Cases**

PLAINTIFFS' MOTION TO COMPEL REGARDING PREEMPTION DISCOVERY

Plaintiffs seek an Order compelling Defendant Genentech to provide responses to their discovery requests related to Genentech's preemption defense.

BACKGROUND

Genentech repeatedly violated Judge Kern's orders governing discovery and has delayed complying with Judge Kern's clear intent to expedite discovery on preemption matters, broadly defined. After the Court has decided issues against Genentech's stated position, Genentech has continually acted contrary to the Court's orders. For example:

- Judge Kern ordered Genentech to provide documents supporting its preemption argument within 10 days: Transcript of Case Management Conference at 31 (June 23, 2016) (Ex. A). Genentech provided no documents or materials within 10 days.

- Judge Kern required Genentech to identify its FDA expert by June 24, 2016. CMO § 5.b.iii. Genentech did not do so until June 30, 2016.

- Judge Kern denied Genentech's objection and entered the Protective Order without an attorney eyes only provision. CMO § 4.c. Yet over 90% of the pages provided in Genentech's limited productions were stamped "attorneys eyes only."

- Genentech sought an order that preemption discovery would not commence until after it filed the Motion for Summary Judgment on preemption (the "Motion"). Judge Kern disagreed and ordered expedited discovery. Yet Genentech has so far provided almost exclusively the documents it intends to rely upon in its Motion and hardly any of the documents Plaintiffs seek for their response brief.

- Genentech refuses to provide for deposition the witness who verified its interrogatory responses, even after Judge Wilson ordered the parties to confer about scheduling the deposition. *See* Notice of Deposition of Stephanie Mendelsohn (July 15, 2016) (Ex. 1). It has indicated that the only witness it will produce is the witness whom Genentech has selected to provide an affidavit in support of its Motion.

A month after the Case Management Conference in which Judge Kern ordered expedited and broadly construed "preemption" discovery, Genentech has provided almost none of that discovery including: no communications between Genentech and the FDA other than the Biologics License Application approved by FDA; no names of individuals involved in the FDA-approval process; no names of individuals involved in measuring the mass of Herceptin or the concentration of reconstituted Herceptin; no specific range of variance of the concentration it contends is permitted by the FDA; no documents, communications, or interrogatory responses concerning its past ability to change the label and prescribing information to provide accurate statements. Plaintiffs seek an order compelling Genentech to comply with the Court's orders and provide the preemption-related discovery sought in Plaintiffs' discovery requests.[1]

ARGUMENT

I. Scope of Preemption Discovery

The federal rules permit discovery on "any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case." Fed. R. Civ. P. 26(b). Judge Kern limited discovery to preemption issues at this time, holding class and merits discovery until later in the case. Genentech urged the Court to narrowly construe discovery on preemption, but Judge Kern did not "agree with the defendant that [discovery is] going to be that narrow." Transcript of Case Management Conference at 26, 32 (June 23, 2016) (Ex. 10). Rather, Judge Kern provided for any discovery on issues that "bear on or reasonably might bear on the question of Federal preemption, and that should be taken in a broader sense." *Id.* Plaintiffs purposely limited

[1] *See* June 24, 2016 Letter from Adams to O'Connor, Donahue and Muelberger (June 24, 2016) (Ex. 2) (renewing the portions of Plaintiffs' Oct. 9, 2015 discovery requests applicable to preemption); Plaintiffs' First Set of Discovery Requests Regarding Preemption (June 28, 2016) (Ex. 3); Genentech's Responses and Objections to The Portions of Plaintiffs' First Set of Discovery Requests Adopted by Plaintiffs Following CMO No. 1 (July 11, 2016) (Ex. 4); Genentech's Responses and Objections to Plaintiffs' First Set of Discovery Requests Regarding Preemption (July 13, 2016) (Ex. 5); Letter from Keglovits to O'Connor, Donahue and Muelberger (July 15, 2016) (Ex. 6); Plaintiffs' Second Set of Discovery Requests Regarding Preemption (July 18, 2016) (Ex. 7); Letter from O'Connor to Keglovits (July 19, 2016) (Ex. 8); Letter from Keglovits to O'Connor, Donahue and Muelberger (July 25, 2016) (Ex. 9).

their discovery requests to: Genentech's interactions with the FDA; Genentech's ability to change its label to comply with both FDA regulations and state warranty laws; Genentech's internal discussions and studies measuring the mass and concentration, both before and after FDA approval of the Herceptin label; and the names of individuals involved in those communications, discussions and decisions. Genentech failed to provide any responsive answer or documents to a majority of those discovery requests. *See* July 15, 2016 Letter (Ex. 6).

II. Discovery Related To Ability To Change Label and Prescribing Information

Information related to Genentech's past ability to change its label and prescribing information will inform Plaintiffs and the Court on the issue of whether Genentech can comply with both FDA regulations and state warranty laws. Specifically, if Genentech can easily make its prescribing information accurate so as to not warrant a mass and/or concentration they do not provide, that would rebut any assertion that it is *impossible* for Genentech to comply with both federal and state law. Plaintiffs requested the communications with the FDA surrounding past label and prescribing information changes, the Changes Being Effected submitted to the FDA, and other similar documents. Genentech provided only the different labels themselves without any communications or documents. *See generally* July 25, 2016 Letter § II (Ex. 9).

For example, Genentech altered its prescribing information in 2000 (after FDA approved its label) to modify one aspect of its commercial terms. The internal discussions and communications with the FDA regarding this change will shed light on whether Genentech could have modified the mass and/or concentration warranties without violating FDA regulations.

III. Discovery Related To Genentech's Decision To Provide FDA Inaccurate Information

While Genentech has produced no internal documents, Plaintiffs possess an internal Genentech email stating that Genentech discussed what concentration to put on its prescribing information and unilaterally decided to misrepresent the number by stating 21 mg/mL instead of 21.8 mg/mL or 22 mg/mL. *See* Email from Tom White to Olivia Ware (Sept. 25, 2002) (Ex. 11) ("Hence the theoretical concentration of the reconstituted product is actually 21.8 mg/ml").

Plaintiffs seek internal documents related to this and other discussions about the representations of mass, concentration and volume included in the prescribing information.

Similarly, Plaintiffs seek documents that may show FDA had concerns with Genentech's representations. This could include correspondence from the FDA to Genentech regarding these representations, or FDA inspection reports, warning letters, or Form 483s.[2] If the FDA, like Plaintiffs, had concerns about the mass, concentration or volume statements, this would undermine Genentech's claim it was impossible to satisfy both FDA and state warranty law. *See generally* July 25, 2016 Letter §§ III, IV (Ex. 9).

IV. Genentech Must Provide Verified Responses To Interrogatories

Genentech has still not provided a sworn answer to what variance it states the FDA permits concerning the mass and concentration warranties. Genentech also failed to provide sworn answers to other basic interrogatories. *See generally* July 25, 2016 Letter § V (Ex. 9).

V. Persons Involved In Measuring The Mass And Concentrations, As Well As Those Communicating With the FDA, Are Relevant To Preemption Discovery

Genentech again ignored the Court's Order and applicable discovery rules by ignoring Plaintiffs' requests to identify persons responsible for:

a. Communicating with FDA during the application process and during each label and prescribing information change.

b. Ensuring the label and prescribing information accurately represent the mass of Herceptin provided and the concentration of reconstituted Herceptin;

c. Removing the prescribing information statement that following Genentech's instructions would yield 21 mL of Herceptin solution;

d. Placing the 440 mg and 21 mg/mL warranties on the label and prescribing information;

e. Determining the concentration of reconstituted Herceptin.

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[2] FDA issues Form 483s to companies at the conclusion of an inspection when an investigator observes any conditions that may violate federal law.

See generally July 25, 2016 Letter § VI (Ex. 9). At the July 25, 2016 meet and confer, Genentech provided only the name of the self-selected corporate spokesperson who will apparently offer an affidavit in support of the Motion, but it refuses to provide any other names responsive to these requests. These discovery requests are not a Rule 30(b)(6) notice, and Genentech cannot simply identify the person whom it wants Plaintiffs to depose and deny Plaintiffs' ability to depose other witnesses with knowledge of the relevant facts.

CONCLUSION

Plaintiffs do not read Judge Kern's ruling to merely require Genentech to give Plaintiffs a "sneak peek" at the evidence it will rely on in its Motion by producing the exhibits and identifying the affiant. Judge Kern's Order—and the federal rules—permit Plaintiffs to obtain documents and verified interrogatory responses relevant to any argument *Plaintiffs* may make in response to Genentech's preemption Motion. Because Plaintiffs have not yet seen the Motion and Genentech's legal arguments have constantly shifted in this case,[3] Plaintiffs must—as Judge Kern recognized—be permitted to conduct discovery as to all matters that may bear on any possible preemption argument Genentech could raise. Plaintiffs are not required to take Genentech's word as to what Plaintiffs need to know. Plaintiffs ask the Court to compel Genentech to provide all of the discovery responsive to the tailored requests made.

[3] For example, Genentech did not even raise preemption in its first or second motions to dismiss. Mot. to Dismiss (Doc. #19 in 15-cv-157) (May 26, 2015); Mot. to Dismiss (Doc. #43 in 15-cv-157) (Oct. 26, 2015).

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of July, 2016, I electronically transmitted the foregoing document to the Clerk of the Court using the CM/ECF System for filing as required in the Court's Practice and Procedure Order (MDL Doc. #6 at ¶5).

/s/ David E. Keglovits
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